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VPI/96-14 CON 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : David M. Naff
Group Art Unit : 1651
Applicants : Alexey L. Margolin et al.
Application No. : 10/760,148
Confirmation No. : 7188
Filed : January 16, 2004
For : CONTROLLED DISSOLUTION CROSSLINKED PROTEIN
CRYSTALS

New York, New York
May 10, 2005

Mail Stop Amendment
Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, Va 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.56 AND § 1.97(b)

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants,
through their attorneys, make of record the following documents,
copies of which are enclosed herewith*:

* A completed Form PTO/SB/08A, listing these documents,
is attached hereto.

United States Patents

4,373,023, Langer et al., issued February 8, 1983
4,579,779, Ohno, issued April 1, 1986
4,606,909, Bechgaard et al., issued August 19, 1986
4,760,025, Estell et al., issued July 26, 1988
5,066,490, Neville et al., issued November 19, 1991
5,120,650, Visuri, issued June 9, 1992
5,286,404, Eriksen et al., issued February 15, 1994
5,385,959, Tsaor et al., issued January 31, 1995
5,500,223, Behan et al., issued March 19, 1996
5,508,164, Kausch et al., issued April 16, 1996
5,569,467, Ruiz, issued October 29, 1996
5,593,697, Barr et al., issued January 14, 1997
5,603,956, Mateescu et al., issued February 18, 1997
5,618,710, Navia et al., issued April 8, 1997
6,140,475, Margolin et al., issued October 31, 2000

PCT Patent Applications

WO 89/06279, published July 13, 1989
WO 92/02617, published February 20, 1992
WO 97/44445, published November 27, 1997
WO 98/13119, published April 2, 1998

European Patent Application

0 341 503, published November 15, 1989

Other Documents

A. Dyer et al., "A thermal investigation of the stability of crystalline cross-linked carboxypeptidase A", Thermochimica Acta, vol. 8, pp. 455-464 (1974).

D.J. Haas, "Preliminary studies on the denaturation of cross-linked lysozyme crystals", Biophysical Journal, vol. 8, pp. 549-555 (1968).

P.J. Kasvinsky et al., "Activity of glycogen phosphorylase in the crystalline state", The Journal of Biological Chemistry, vol. 251, No. 21, pp. 6852-6859 (1976).

J.J. Lalonde et al., "Cross-linked crystals of candida rugosa lipase: highly efficient catalysts for the resolution of chiral esters", No. 26, Journal of the American Chemical Society, vol. 117, pp. 6845-6852 (1995).

K.M. Lee et al., "Crosslinked crystalline horse liver alcohol dehydrogenase as a redox catalyst: activity and stability toward organic solvent", Bioorganic Chemistry, vol. 14, pp. 202-210 (1986).

A.L. Margolin, "Novel crystalline catalysts," TIBTECH vol. 14, pp. 223-230 (1996).

N.L. St. Clair et al., "Cross-linked enzyme crystals as robust biocatalysts", Journal of the American Chemical Society, vol. 114, pp. 7314-7316 (1992).

V.P. Torchilin et al., "Principles of enzyme stabilization. V. Possibility of enzyme selfstabilization under the action of potentially reversible intramolecular cross-linkages of different length," Biochimica et Biophysica Acta, vol. 568, pp. 1-10 (1979).

E. Tuchsén et al., "Kinetic properties of subtilisin type carlsberg in the crystalline state," Carlsberg Research Communications, vol. 42, pp. 407-420 (1977).

K. Xu et al., "pH Control of the catalytic activity of cross-linked enzyme crystals in organic solvents", No. 41, Journal of the American Chemical Society, vol. 118, pp. 9815-9819 (1996).

A. Yonath et al., "Crystallographic studies of protein denaturation and renaturation", Biochemistry, vol. 16, No. 7, pp. 1413-1417 (1977).

Derwent Japanese Patent Abstract XP-0002066465, JP860159799, published 1988.

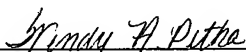
Fluka Catalogue, "Reagents for protein modification," Chapter Crosslinkers, pp. 61-67 (1986).

All of the aforementioned documents are listed on the accompanying Form PTO/SB/08A (submitted in duplicate). Pursuant to the U.S. Patent and Trademark Office's waiver of the requirement under 35 C.F.R. §1.98(a)(2)(i) for all U.S. national patent applications filed after June 30, 2003, copies of issued requirement under 35 C.F.R. §1.98(a)(2)(i) for all U.S. national patent applications filed after June 30, 2003, copies of issued U.S. patents and published U.S. patent applications are not provided. Copies of all foreign patent documents and all other documents cited above are provided.

Applicants request that these documents: (1) be fully considered by the Examiner during examination of this application and (2) be printed on any patent that may issue from this application. Applicants also request that a copy of Form PTOSB/08A, as considered and initialed by the Examiner be returned with the next communication.

The Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075, Order No. (003662-0014). A duplicate copy of the accompanying transmittal letter setting forth that authorization is transmitted herewith.

Respectfully submitted,


James F. Haley, Jr. (Reg. No. 27,794)
Margaret A. Pierri (Reg. No. 30,709)
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TRANSMITTAL LETTER FOR
INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.56 in the above-identified application. This Statement is being submitted before the mailing of a first Office Action on the merits under 37 C.F.R. § 1.97(b)(3).

In accordance with 37 C.F.R. § 1.97(b)(3), applicants believe that submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fee required in

connection with this Information Disclosure Statement to
Deposit Account No. 06-1075, Order No. (003662-0014). A
duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

Wendy A. Petka

James F. Haley, Jr. (Reg. No. 27,794)

Margaret A. Pierri (Reg. No. 30,709)

Attorneys for Applicants

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I hereby certify that this
Correspondence is being
deposited with the U.S.
Postal Service as First
Class Mail in an envelope
Addressed to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450 on

5-10-05

Gene Kesselman
Signature of Person Signing



PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/760,148
Confirmation Number	7188
Filing Date	January 16, 2004
First Named Inventor	Alexey L. Margolin et al.
Art Unit	1651
Examiner Name	David M. Naff
Attorney Docket Number	VPI/96-14 CON 2

Sheet 1 of 2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		4,373,023	2/8/83	Langer et al.	
		4,579,779	4/1/86	S. Ohno	
		4,606,909	8/19/86	Bechgaard et al.	
		4,760,025	7/26/88	Estell et al.	
		5,066,490	11/19/91	Neville et al.	
		5,120,650	6/9/92	K. Visuri	
		5,286,404	2/15/94	Eriksen et al.	
		5,385,959	1/31/95	Tsaur et al.	
		5,500,223	3/19/96	Behan et al.	
		5,508,164	4/16/96	Kausch et al.	
		5,569,467	10/29/96	J.M. Ruiz	
		5,593,697	1/14/97	Barr et al.	
		5,603,956	2/18/97	Mateescu et al.	
		5,618,710	4/8/97	Navia et al.	
		6,140,475	10/31/00	Margolin et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Country	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		WO 89/06279	7/13/89	PCT		
		WO 92/02617	2/20/92	PCT		X
		WO 97/44445	11/27/97	PCT		X
		WO 98/13119	4/2/98	OCT		X
		EP 0 341 503	11/15/89	EPO		X

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		A. Dyer et al. "A thermal investigation of the stability of crystalline cross-linked carboxypeptidase A," <i>Thermochimica Acta</i> , vol. 8, pp. 455-464 (1974) .	
		D.J. Haas, "Preliminary studies on the denaturation of cross-linked lysozyme crystals," <i>Biophysical Journal</i> , vol. 8, pp. 549-555 (1968) .	
		P.J. Kasvinsky et al. "Activity of glycogen phosphorylase in the crystalline state," <i>The Journal of Biological Chemistry</i> , vol. 251, pp. 6852-6859 (1976).	

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
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Sheet	2	of	2	Attorney Docket Number	VPI/96-14 CON 2

	J.J. Lalonde et al., "Cross-linked crystals of candida rugosa lipase: highly efficient catalysts for the resolution of chiral esters," <u>Journal of the American Chemical Society</u> , vol. 117, p. 6845-6852 (1995).	
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	A. L. Margolin, "Novel crystalline catalysts," <u>TIBTECH</u> , vol. 14, pp. 223-230 (1996).	
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	K. Xu et al., "pH control of the catalytic activity of cross-linked enzyme crystals in organic solvents," <u>Journal of the American Chemical Society</u> , vol. 118, pp. 9815-9819 (1996).	
	A. Yonath et al. "Crystallographic studies of protein denaturation and renaturation," <u>Biochemistry</u> , vol. 16, pp. 413-417 (1977).	
	V.P. Torchilin et al. "Principles of enzyme stabilization. V. Possibility of enzyme selfstabilization under the action of potentially reversible intramolecular cross-linkages of different length," <u>Biochimica et Biophysica Acta</u> , vol. 568, pp. 1-10 (1979).	
	Derwent Abstract 88-061232 of Japanese Patent Application 63017691, published September 1988.	
	Fluka Catalogue, "Reagents for protein modification", Chapter Crosslinkers, pp. 61-67 (1986).	

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

Examiner Signature	Date Considered
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